

354. Adulteration and misbranding of halibut liver oil capsules. U. S. v. 24,000, 75,000, and 90,000 Halibut Liver Oil Capsules. Consent decrees of condemnation. Product ordered released under bond for relabeling. (F. D. C. Nos. 2051, 2052, 2054. Sample Nos. 33424-E, 33425-E, 33426-E.)

This product was represented to consist of halibut liver oil but consisted in part of other fish-liver oil.

On June 1 and 3, 1940, the United States attorneys for the Southern District of New York and the Eastern District of New York filed libels against a total of 99,000 halibut liver oil capsules at New York, N. Y., and 90,000 halibut liver oil capsules at Brooklyn, N. Y., alleging that the article had been shipped in interstate commerce within the period from on or about October 5, 1939, to on or about February 14, 1940, by the White Laboratories, Inc., from Newark, N. J.; and charging that it was adulterated and that portions were also misbranded. Portions were labeled in part: "Halibut Liver Oil Capsules * * * Halibut Plain," or "Halibut Liver Oil Pl."

All lots of the article were alleged to be adulterated in that another fish-liver oil had been wholly or in part substituted for plain halibut-liver oil. All lots were alleged to be misbranded in that they were offered for sale under the name of another drug. Portions were alleged to be misbranded further in that the statements, "Halibut Liver Oil * * * Capsules," "Halibut Liver Oil Plain," and "Halibut Liver Oil Pl.," were false and misleading, since the article did not consist of halibut liver oil but was a mixture of fish-liver oils.

On June 25, 1940, White Laboratories, Inc., claimant, having admitted the allegations of the libels, judgments of condemnation were entered, and it was ordered that the product be released under bond conditioned that it be relabeled so as to declare that the capsules contained halibut-liver oil which had been mixed with another fish oil.

355. Adulteration and misbranding of Estrinol in oil. U. S. v. 118 Ampuls of Estrinol in Oil. Default decree of condemnation and destruction. (F. D. C. No. 2500. Sample No. 3064-E.)

Each cubic centimeter of this product was represented to possess an activity equivalent to 5,000 International Units of estrogenic substance, whereas it was inert.

On August 7, 1940, the United States attorney for the Western District of Pennsylvania filed a libel against 118 ampuls of Estrinol in oil at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about March 8, 1940, by the Bellevue Laboratories, Inc., from New York, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely: (Label) "1 CC is therapeutically equivalent to 5,000 I. U. of estrogenic substance." It was alleged to be misbranded in that the statement on the label, "1 CC is therapeutically equivalent to 5,000 I. U. of estrogenic substance," was false and misleading as applied to an article which was inert.

On September 25, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

356. Adulteration and misbranding of Shores Ka-Vi-Min Tablets. U. S. v. 1½ Drums Containing 71,300 Tablets of Shores Ka-Vi-Min Tablets. Default decree of condemnation and destruction. (F. D. C. No. 3992. Sample No. 32805-E.)

This product was labeled as containing 140 U. S. P. units of vitamin D and 25 International Units of vitamin B₁ per tablet; whereas it contained not more than 100 U. S. P. units of vitamin D and not more than 15 U. S. P. units of vitamin B₁ (1 U. S. P. unit of vitamin B₁ is equal to 1 International Unit of the same vitamin).

On March 14, 1941, the United States attorney for the Southern District of California filed a libel against 1½ drums of Shores Ka-Vi-Min Tablets at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about February 28, 1940, by the Shores Co. from Cedar Rapids, Iowa; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess. It was alleged to be misbranded in that the following statements were false and misleading, since each tablet did not contain 140 U. S. P. units of vitamin D or 25 International Units of vitamin B₁: "Each tablet contains * * * 140 USP units Vitamin D" and "25 International units Vitamin B₁." The article was also

charged to be adulterated and misbranded under the provisions of the law applicable to food, as reported in notices of judgment on foods.

On April 14, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

357. Adulteration and misbranding of Sea-Clo-400-D. U. S. v. 4 Cans of Sea-Clo-400-D. Default decree of condemnation and destruction. (F. D. C. No. 1611. Sample No. 78465-D.)

This veterinary product contained not more than 200 A. O. A. C. chick units of vitamin D per gram and contained less than 500 U. S. P. units of vitamin A; whereas it was represented in the labeling that it contained 400 A. O. A. C. units of vitamin D per gram and that it contained substantially 1,000 units of vitamin A per gram.

On March 14, 1940, the United States attorney for the Northern District of West Virginia filed a libel against 4 50-pound cans of Sea-Clo-400-D at Martinsburg, W. Va., alleging that the article had been shipped in interstate commerce on or about January 2, 1940, by Sea Board Supply Co., Inc., from Philadelphia, Pa.; and charging that it was adulterated and misbranded. It was labeled in part: "Sea-Clo-400-D Highly Fortified Cod Liver Oil in Dry Base."

The article was alleged to be adulterated in that its strength differed from and its purity fell below that which it purported or was represented to possess, that is, it was labeled: "Guaranteed to contain 400 A. O. A. C. units of Vitamin D per gram. When this product is packed it contains more than 1000 Units of Vitamin 'A' per gram, but due to a difference of opinion of our many Authorities regarding the stability of Vitamin 'A' from Cod Liver Oil when added to feeds, we are making no claim for it."

It was alleged to be misbranded in that the following statements appearing on the label were false and misleading: "Sea-Clo-400-D * * * In place of each 4½ lbs. straight 85-D Oil, use 1 lb. Sea-Clo-400-D. In place of each 1 lb. Fortified 400-D Oil, use 1 lb. Sea-Clo-400-D. For each 5 pints 85-D Oil used, replace with 1 lb. Sea-Clo-400-D."

On November 27, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING THERAPEUTIC CLAIMS

DRUGS ALSO FAILING TO BEAR COMMON OR USUAL NAME OR REQUIRED INGREDIENT STATEMENT

358. Misbranding of Alpine Tea. U. S. v. 57 Packages of Alpine Tea. Default decree of condemnation and destruction. (F. D. C. No. 3219. Sample No. 26435-E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated below. The statement of analysis on the label was misleading since it represented the analysis of the ash and not of the tea itself. Its label also failed to bear a statement of its common name.

On October 21, 1940, the United States attorney for the District of Oregon filed a libel against 57 packages of Alpine Tea at Rainier, Oreg., alleging that the article had been shipped in interstate commerce by the Alpine Tea Co. on or about September 2, 1939, from Detroit, Mich.; and charging that it was misbranded.

Analysis showed that the article consisted of cut dried leaves of blueberry.

The article was alleged to be misbranded in that representations in the labeling that it would be efficacious to balance the deficiency of body minerals; stimulate the pancreatic glands, kidneys, bladder, and liver; increase vitality amazingly and almost immediately, which increase would continue throughout the day; would help one get a good night's rest; would serve as an effective aid to the diabetic's diet, and would decrease the need for insulin; and that it was not only efficacious for diabetics but was also good for other ailments such as those of the liver, spleen, kidneys, bladder, and for stomach ulcers, were false and misleading since it would not be efficacious for such purposes.

It was alleged to be misbranded further in that the following statements in the labeling, (carton) "Analysis: Silica (SiO₂) 10.99%; Iron Oxide (Fe₂O₃) 1.90%; Manganese Oxide (Mn₂O₄) 5.10%; Aluminum Oxide (Al₂O₃) 11.38%; Calcium Oxide (CaO) 21.84%; Magnesium Oxide (MgO) 7.27%; Sodium Na (as Na₂O) 7.11%; Potassium K (as K₂O) 10.06%; Sulphate (SO₃) 5.32%; Phosphate (P₂O₅) 5.86%; Carbonate (60₂) 10.17%; Chloride (Cl) 2.00%; Free